APR - 1 2004

510 (K) SUMMARY

K024186

SUBMITTER: **SOMETECH CORPORATION**
6669 Peachtree Industrial Blvd
Suite J
Norcross, Georgia 30092
phone: 770-825-0100 / fax: 770-849-9733

Contact Person: **Mr. Ki Cheol Han**

Date: **March 30, 2004**

Device Name: **X-View**

Device Description

X_View device consists of 3 components: the sensor and its cable, data box, and a PC with sensor adapter. The sensors outer body is made of hermitically sealed polymer shell which encapsulates a black and white CCD. The sensor attaches to the processing unit via a 3 m cable. The outer dimensions are approximately 40 x 25 x 5 mm with rounded edges.

The Data box relays the data to the computer for display. The data box is white 4 x 9 inch box with a 5 ft USB cable connection.

Intended Use

The X-View device is used to provide instant images of human oral tissue and teeth without the use of conventional x-ray film.

This is achieved by using the conventional x-ray tube, and placing an electronic sensor in the patients mouth instead of film. The sensor automatically captures the images into a computer for viewing, storage or printing. The computer controls all aspects of image acquisition and image display. These functions would include a full mouth display, zoom functions, contrast controls, image inversion, brightness, and pseudo color renditions.

The X-View System is used to provide instant images of x-rayed human oral tissue and teeth without the use of conventional x-ray films. The sensor, upon radiation exposure, Captures the images into a computer for viewing, storage, and printing

Just like Trophy's RVG (K962337) and Regam's Sens-A-Ray (K923067)
X-View is similar in its intended use. The X-View System, along with the aforementioned other systems, consists of a sensor and its cable, a sensor adapter, and a personal computer. The sensor and cable are fully waterproof (IXP 7 standard) and may be sterilized by full immersion in a disinfectant solution. The sensor's outer body is made of hermetically sealed polymer shell, which encapsulates a black and white CCD. It has an active sensitive area of 600 mm2, an image matrix of 960,000 pixels and renders a minimum 15 lines / mm and a maximum 18 lines /mm. The X-View System, along with Sens-A-Ray and RVG, is able to collect images in real – time enabling the dental practice to put more emphasis on the patient Digital media is faster and easier to store. The computer, along with the resident software controls all aspects of image acquisition and display.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Mr. Ki Cheol Han
President
Sometech Corporation
6669 Peachtree Industrial Blvd., Suite J
NORCROSS GA 30092

Re: K024186
Trade/Device Name: X-View
Regulatory Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory class: II
Product Code: 90 MUH
Dated: January 2, 2004
Received: January 2, 2004

Dear Mr. Han:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K024186

Device Name: X - VIEW

Indications for Use: The X – VIEW System is a device used to provide instant images of the human oral tissue and teeth without the use of conventional x-ray films. While an X-Ray machine is still utilized, the acquisition of an image requires up to 90% less radiation than a conventional system would require to produce the same image.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024186